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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,979	10/24/2003	William R. Campbell	PIED1110-1	1729
7590 STACY L. TAYLOR DLA PIPER US LLP Suite 1100 4365 Executive Drive San Diego, CA 92121-2133				
EXAMINER LEVY, NEIL S				
ART UNIT 1615		PAPER NUMBER		
MAIL DATE 06/22/2011		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/692,979

**Applicant(s)**

CAMPBELL ET AL.

**Examiner**

NEIL LEVY

**Art Unit**

1615

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5/17/2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 12-16 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-16 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 12-15 stand rejected under 35 U.S.C. 103(a) as obvious over SINGER et al 4147800

IPM (Table 1) at about 70%, with polysorbate and water carrier, killed 100% lice (column 4, lines 21-32). Table I shows 82- 100% killed with 70 -78% IPM. Examples are with human lice, obviously inclusive of all species. Curve 2 is only IPM (COL. 4, LINE 23-26) & POLYSORBATE @ 70%, WITH DEATH IN A 2 MINUTE TEST thus meeting the instant claims. NO OTHER AGENTS are needed, only IPM. As to the retention, examples show shampoos, lotions. Only shampoos would have a short time of retention, but lotions would be applied as is known in the art, without intentional removal; thus, retention of hours.

Polysorbate is an inert surfactant-it does not have a detrimental effect on the pediculocidal toxicant activity (col 3, top). It is not excluded from the instant claims, which do not exclude anything but alcohol and insecticides. Polysorbate is neither. "At least up to" includes zero. "At least" could be taken to mean at least one louse was killed. The reference shows synergistic effects. Alcohol and IPM kill 100%. Applicant only kills up to 82%.

SINGER already knew that IPM could kill all lice (100%) if 100% IPM was used, for only 2 minutes. SINGER also states other concentrations are pediculocidal (col 4, lines 45-52). Contrary to applicant's arguments, the whole reference was considered.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize pest control means, to use any of art recognized means, as of the ectoparasitidal, pediculicide compositions to control lice, modified as desired to decrease toxicity to patients.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability. Applicant's concentrations at the high end are lethal; at the low end are neither shown in the specification to be effective, nor are they shown by SINGER to be effective @ the 82 %, or less, mortality level .

Claims 1-4, 12-15, 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over SINGER et al 4147800 in view of REID et al 5972987

SINGER (above) kills lice, but does not mention combing.

REID shows application of pediculicide and dye (column 4, lines 6-11) permit removal with combs (column 4, lines 50-56) from human or animal (lines 63-66) particularly head lice (column 5, lines 44-48). Example 1 shows use of silicone and IPM.

REID teaches killing lice does not solve the problem of dead lice or nits (col 2, lines 55-64). REID adds dye, to insure complete removal (col 3, lines 12-37). Typical process of

removing lice is application of a pediculocide, usually as cream or shampoo (col 5, lines 30-38) followed by combing with a very fine-toothed comb. REID provides an improvement over this typical process. The instant claims require only combing.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize pest control means, to use any of art recognized means, as of the pediculicide compositions of SINGER to control lice, modified as desired to decrease toxicity to patients. Motivation to combine springs from the IPM synergy of SINGER, with further removal of lice and nits facilitated by dye and comb of REID.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or the manner of treating lice, combing, shampooing, rinsing, or ingredient concentrations provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability

***Claim Rejections - 35 USC § 102***

Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by SINGER.

IPM (Table 1) at about 70%, with polysorbate and water carrier, killed 100% lice (column 4, lines 21-32). Table I shows 82- 100% killed with 70 -78% IPM. Examples

are with human lice, obviously inclusive of all species. Curve 2 is only IPM (COL. 4, LINE 23-26) & POLYSORBATE @ 70%, WITH DEATH IN A 2 MINUTE TEST thus meetingThe instant claims. NO OTHER AGENTS are needed, only IPM. As to the retention, examples show shampoos, lotions. Only shampoos would have a short time of retention, but lotions would be applied as is known in the art, without intentional removal; thus, retention of hours.

Alcohol is permitted in the instant claims. Alcohol is not considered an insecticide, and is not excluded. The compositions of SINGER kill more than "at least up to" of the instant when applied in an inert carrier (Fig. 1, 2, and 3).

How they kill or what else they do is a function of the composition characteristics, and not of patentable weight. If the lice all die within 48 hours, the 10-minute administration of the instant has been met.

### ***Response to Arguments***

Applicant's arguments filed 5/17/2011 have been fully considered but they are not persuasive. Applicant's arguments have been considered in the above rejections. The amendments are less restrictive than previously rejected claims. However, VonBITTERA is difficult to include, as attorney points out, without consideration of the active insecticides, so it is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is (571)272-0619. The examiner can normally be reached on Tuesday-Friday, 7:15AM to 5:45 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT A. WAX can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/  
Primary Examiner, Art Unit 1615 6/20/2011